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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC., *et al.*, **Plaintiffs,** **v.** **ROXANE LABORATORIES, INC.,** **Defendant.**	**Civil Action No. 15-1360 (ES)(JAD)** **(Filed Electronically)**

JAZZ PHARMACEUTICALS' RESPONSIVE *MARKMAN* BRIEF

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Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz") submit this responsive brief in support of their proposed constructions of the disputed terms of United States Patent Nos. 8,772,306 ("the '306 patent") and 9,050,302 ("the '302 patent") (collectively, the "'306 patent family") owned by Jazz.[1]

I. INTRODUCTION

The only disputed term remaining is "concomitant." Both parties agree that the inventor of the '306 patent family acted as his own lexicographer by defining the term. The parties disagree, however, concerning what definition the inventor provided. Roxane's construction improperly seeks to read examples from the specification of the '306 patent family into the claims. This violates Federal Circuit precedent holding that courts should never limit claims to preferred embodiments in the specification absent a clear and unequivocal disclaimer of claim scope. There is no such disclaimer here. Further, Roxane's claim that Jazz's construction of "concomitant" introduces ambiguity is based solely on unsupported attorney argument. Moreover, Jazz and four other generic defendants in *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, Civ. No. 13-391 ("Civ. No. 13-391") all agree that Jazz's construction of "concomitant" here is the proper construction of the term. (*See* Ex. 4, Civ. No. 13-391, D.I. 315 at 4.)[2] Roxane is the only party that refuses to accept the lexicography in the specification and instead sets forth a strained, litigation-contrived construction. Here, the specification's explicit definition of "concomitant" should be both the beginning and the end of the Court's inquiry.

[1] Jazz has agreed to withdraw U.S. Patent No. 8,461,203 ("the '203 patent") from the litigation. Therefore, the terms "admix" and "contacting" from the '203 patent (*see* D.I. 83 at 5-10; D.I. 84 at 4-9) are no longer in dispute.

[2] "Ex. 4" herein refers to the exhibit to the Declaration of Gabriel P. Brier in support of Jazz's Responsive *Markman* Brief, submitted herewith.

II. ARGUMENT

A. "Concomitant"

"concomitant"	
Jazz's construction	**Roxane's construction**
"the administration of at least two drugs to a patient either subsequently, simultaneously, or consequently within a time period during which the effects of the first administered drug are still operative in the patient"	"administration of a drug product to a single patient either subsequently, simultaneously, or consequently within two weeks of administration of a second product"

As explained in Jazz's opening claim construction brief, "Concomitant" is explicitly defined in the '306 patent's specification as follows:

> "Concomitant" and "concomitantly" as used herein refer to the administration of at least two drugs to a patient either subsequently, simultaneously, or consequently within a time period during which the effects of the first administered drug are still operative in the patient.

(Ex. 3, '306 patent at 8:37-41.)[3] Roxane ignores this definition and instead argues that the specification expressly defined "concomitant" to include a two week time limit based on the following examples: :

> Thus, if the first drug is, e.g., Xyrem®, or GHB, and the second drug is valproate, the concomitant administration of the second drug occurs within two weeks, preferably within one week or even three days, before or after the administration of the first drug.

(D.I. 83 at 12.) Specifically, Roxane improperly seeks to re-write the specification's definition as follows:

[3] "Ex. 1" through "Ex. 3" herein refers to the exhibits to the Declaration of Gabriel P. Brier in support of Jazz's Opening *Markman* Brief, submitted on November 4, 2016. (D.I. 84-1.)

> "Concomitant" and "concomitantly" as used herein refer to the administration of ~~at least two drugs~~ a drug to a single patient either subsequently, simultaneously, or consequently ~~within a time period during which the effects of the first drug are still operative in the patient~~ within two weeks of administration of a second drug.

First, Roxane seeks to strike the portion of the lexicography reciting "within a time period during which the effects of the first drug are still operative in the patient" and replace it with "within two weeks of administration of a second drug." (*Id.*) Roxane bases its re-write of the lexicography solely on the example from the specification. (*See id.* (citing '306 patent at 8:41-45).) Roxane's argument violates one of the most fundamental tenets of claim construction: patent examples should not be used to limit the scope of a claim term absent a clear disavowal. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments."); *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986) ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification.").

Here, Roxane attempts to use a preferred embodiment (indicated by the word "preferably") to read limitations into the claim term. However, Roxane cannot identify any clear disavowal of claim scope that would limit the term "concomitant" to "administration of a drug . . . within two weeks of administration of a second drug" (*see* D.I. 83 at 12). *See Decisioning.com, Inc. v. Federated Dep't Stores Inc.*, 527 F.3d 1300, 1314 (Fed. Cir. 2008) (holding that there must be a clear intention to limit claim scope); *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009) (holding that a narrowing construction requires a clear and unmistakable disavowal of claim scope). Thus, Roxane's attempt to read in a "within two week" limitation into the term "concomitant" is improper.

Second, Roxane seeks to re-write the portion of the lexicography reciting "to a patient" to recite "to a ***single*** patient." Roxane's attempt should be rejected as an unnecessary exercise in redundancy. *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). Indeed, Roxane previously attempted to read the limitation "to an ***individual*** patient" into the phrase "dispensed to the patient." (Ex. 2, Civ. No. 10-6108, D.I. 151 at 40-41.) There, the Court found "no direct support for the limitations set forth by Roxane, and it [found] that the limitation 'to an individual patient' injects redundancy." (*Id.* at 41.) The Court should do the same here.

Finally, Roxane baselessly alleges that Jazz's construction of "concomitant" "adds ambiguity and subjectivity because a POSA would not have known how to tell if 'the effects of the first administrated drug are still operative in the patient.'" (D.I. 83 at 13-14.) As stated above, five out of the six parties litigating the '306 patent family all agree that Jazz's construction is not "ambigu[ous]," as Roxane alleges (*id.*). (*See* Ex. 4, Civ. No. 13-391, D.I. 315 at 4.) Instead, Roxane alone feigns ignorance at how a skilled artisan would "assess what 'effects' are to be measured and how to determine if those 'effects' are 'still operative' in the patient after administration of the first drug." (*See* D.I. 83 at 13-14.) Roxane's position is simply irrelevant to claim construction.[4]

Also, determining the scope of the claims would be readily apparent to either party's definition of a person of ordinary skill in the art ("POSA"). Roxane proposes that a POSA would have:

> at least a Ph.D., Doctor of Pharmacy degree, or medical degree, and five years of experience treating patients with neurologic disorders, including at least cataplexy or excessive daytime sleepiness in narcolepsy and/or five years of experience regarding drug metabolism, pharmacokinetics, and/or pharmacodynamics; a POSA may also include a clinical pharmacologist with at least

[4] To the extent Roxane is raising an argument of "indefiniteness" in a *Markman* brief rather than through its invalidity contentions, that argument is untimely.

> three years of experience consulting with physicians on the dosing of drugs in light of potential drug-drug interactions, comorbid conditions, or other factors that could affect dosing.

(D.I. 83 at 11.) While Jazz disagrees, it makes little difference here.[5] Under either party's definition of a POSA, based on the context of the specification, such a skilled artisan would be able to assess whether the effects of the first administered drug were still operative at the time of administration of the second drug. Thus Roxane's indefiniteness argument lacks merit.

Accordingly, Roxane's proposed construction of "concomitant" should be rejected. The specification's explicit definition of "concomitant" should be both the beginning and the end of the Court's inquiry. (*See* D.I. 84 at 10-11.)

III. CONCLUSION

For the foregoing reasons, Jazz respectfully requests that the Court adopt its proposed definition of the disputed claim term.

[5] Jazz proposes that a POSA concerning the '306 and '302 patents would be a medical doctor practicing for at least 4-6 in the field of sleep disorders, and would have either: (1) at least two years' experience related to drug pharmacology or (2) access to those with at least two years' experience related to drug pharmacology.

Dated: November 18, 2016

By: s/ Charles M. Lizza

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